

## **REMARKS**

By this Amendment, claims 18-22 and 32 are canceled, without prejudice or disclaimer, and claims 23-25, 28, and 29 are amended. Consequently, claims 23-31 are pending in this application.

As an initial matter, Applicants take this opportunity to thank the Examiner for indicating that, upon overcoming a 35 U.S.C. § 112, second paragraph, rejection, claim 29 contains allowable subject matter. In light of that indication, Applicants rewrote claim 29 in independent form, with an appropriate amendment to overcome the 35 U.S.C. § 112, second paragraph, rejection to place this claim in condition for allowance.

For the following reasons, Applicants respectfully request reconsideration and withdrawal of all objection and rejections outstanding in the June 15, 2005 Office Action.

### **Objection to Specification**

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter under 37 C.F.R. § 1.75(d)(1). In particular, the Office Action asserts that the subject matter recited in now-canceled claim 20<sup>1</sup> lacks antecedent basis in the specification. Although Applicants do not necessarily agree with this objection, Applicants note that this objection is rendered moot by cancellation of claim 20. Thus, Applicants respectfully request reconsideration and withdrawal of this objection to the specification.

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<sup>1</sup> The Office Action does not specifically identify the claim(s) to which this objection applies. Applicants note that the objected subject matter appears in claim 20 (now-canceled) and, therefore, presume that the Office Action intended to apply this objection to the specification in view of claims 20.

The Office Action also asserts that, “there are no embodiments disclosed that have the tissue displacement device being an anvil portion and a tissue displacement portion pivotally coupled to the anvil portion, along with the fastening device.” The Office Action again does not specifically identify the claim(s) to which this objection applies. Applicants note that the objection may apply to claim 31.

Applicants also note that it is unclear whether this assertion is made as a part of the above-discussed objection to the specification (i.e., for lacking proper antecedent basis) or as a separate objection. Regardless of its status or purpose, Applicants respectfully note that there is no requirement that a single embodiment must disclose all of the various aspects of a claimed invention. Even though an embodiment of a device may not be shown or described to include a certain aspect of the claimed invention, that does not necessarily mean that the omitted aspect cannot not be included in, or be used in connection with, that embodiment. Nor is there any requirement that the words in the claim must match those used in the specification disclosure, as long as the terms and phrases define the invention with a reasonable degree of clarity and precision.

This application as filed adequately discloses various exemplary embodiments of the tissue displacement device, with or without figures. Those embodiments include a tissue displacement device having an anvil portion and a tissue displacement portion pivotally coupled to the anvil portion, as shown in, for example, Figs. 17b and 17c. In addition, the tissue displacement device 22 depicted in Figs. 2 and 3 may replace, or be used in conjunction with, at least portion of the fundoplication device 120 of Figs. 17b-17c. Similarly, the fastener delivery device 24 shown in, for example, Figs. 5-7 may be used in any of the exemplary devices disclosed in the application.

For these reasons, Applicants respectfully request reconsideration and withdrawal of this objection to the specification.

**35 U.S.C. § 112, Second Paragraph, Rejection**

Claims 18-22, 28, and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner asserts that: (a) the term “tissue displacement portion” in claim 18 lacks antecedent basis; (b) the term “fastener delivery device” in claim 28 lacks antecedent basis; and (c) it is unclear if the fastener is being positively recited in claim 29.

With respect to item (a) above, Applicants note that this ground of rejection is rendered moot by cancellation of claim 18. With respect to item (b), Applicants amended claim 28 appropriately to supply proper antecedent basis. With respect to item (c), Applicants amended claim 29 to positively recite a fastener. Applicants believe that all pending claims fully comply with the requirements of 35 U.S.C. § 112, second paragraph.

Thus, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

**35 U.S.C. § 102(e) Rejection Based on Kortenbach**

Claims 18-23, 25-27, and 30-32 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,086,600 to Kortenbach (Kortenbach). For the following reason, Applicants respectfully request reconsideration and withdrawal of this rejection.

Independent claim 23 is directed to a device for performing endoluminal fundoplication. The device comprises, among other things, “a flexible tube having a distal end adapted for insertion in the stomach through the esophagus,” “a tissue

displacement device disposed adjacent the distal end of the flexible tube and configured to press a fundus wall of the stomach towards the esophageal wall, so as to form an intussusception of the esophagus into the stomach,” and “a fastening device configured to pass through a lumen of the flexible tube relative to the tissue displacement device.”

Kortenbach discloses an endoscopic surgical instrument including a flexible tube 12 and a grasping and fastening end effector 18 coupled to the distal end of the tube 12. The end effector 18 has a stationary member 31, a rotatable fastener head 40, and a grasper 42. The rotatable fastener head 40 includes a store of female fastener parts 57, and the stationary member 31 includes a store of male fastener parts 46 and a rotatable firing member 52 for ejecting the male fastener 46, as shown in, for example, Figs. 4-6.

In rejecting the claims, the Office Action asserts that the fastener head 40 (or the grasper 42) and the firing member 52 (or the stationary member 31) of Kortenbach allegedly correspond to the recited “tissue displacement device” and “fastening device,” respectively. As is apparent, however, the firing member 52 or the stationary member 31 of Kortenbach is not configured to pass through a lumen of a flexible tube (e.g., the flexible tube 12) relative to the fastener head 40 or the grasper 42 that are disposed adjacent the distal end of that tube. Instead, the firing member 52 and the stationary member 31 necessarily move together with the fastener head 40 and the grasper 42 because all of these elements are part of the end effector 18.

For at least this reason, claim 23 and its dependent claims patentably distinguish from Kortenbach. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

**35 U.S.C. § 102(b) or §103(a) Rejection based on Harrison**

Claims 18 and 20-22 are rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over, U.S. Patent No. 5,403,326 to Harrison et al. Without necessarily acquiescing to this rejection, Applicants note that this rejection is rendered moot by cancellation of claims 18 and 20-22. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

**35 U.S.C. § 102(e) or §103(a) Rejection based on Laufer**

Claims 18, 20-23, 25-27, and 30-32 are rejected under 35 U.S.C. § 102(e) as being anticipated by or, in alternative, under 35 U.S.C. § 103(a) as being obvious over, U.S. Patent No. 6,663,639 to Laufer et al. (Laufer). For the following reason, Applicants respectfully request reconsideration and withdrawal of this rejection.

As discussed above, independent claim 23 recites, among other things, “a fastening device configured to pass through a lumen of the flexible tube relative to the tissue displacement device.”

Laufer discloses a device for reconfiguring a tissue within a hollow body organ. As shown in, for example, Fig. 25, the device includes an inner tube 280, a concentric outer tube 290, a pair of grasper arms 210, a pair of stapler arms 230, a stapler cartridge 260, and a stapler anvil 270.

In rejecting the claims, the Office Action asserts that either one of the stapler arms 230 (or the tissue securing device 22 shown in Fig. 7) allegedly corresponds to the recited “tissue displacement device.” The Office Action does not specifically point out which element of Laufer corresponds to the recited “fastening device.” Nonetheless, it

appears that the element in Laufer that is configured to insert a fastener is the stapler cartridge 260 or the stapler cartridge 260 in combination with the stapler anvil 270.

As is abundantly clear, however, like the device of Kortenbach discussed above, the stapler cartridge 260 or the stapler anvil 270 of Laufer is not configured to pass through a lumen of a flexible tube (e.g., the inner tube 280 or outer tube 290) relative to the stapler arms 230 that are disposed adjacent the distal end of that tube, because the stapler cartridge 260 and the stapler anvil 270 are fixed to the stapler arms 230.

For at least this reason, claim 23 and its dependent claims patentably distinguish from Laufer. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

**35 U.S.C. § 103(a) Rejection based on Laufer and Carroll**

Claims 24 and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Laufer in view of U.S. Patent No. 6,066,146 to Carroll et al. (Carroll).

Each of dependent claims 24 and 28 directly depends from independent claim 23, and thus includes all recitations thereof. As discussed above, independent claim 23 patentably distinguishes from Laufer. That is, Laufer does not disclose, among other things, “a fastening device configured to pass through a lumen of the flexible tube relative to the tissue displacement device,” as recited in independent claim 23. Carroll discloses a laparoscopic incision closure device and, thus, does not supply the deficiency of Laufer. Therefore, claims 24 and 28 also patentably distinguish from the alleged combination of Laufer and Carroll at least by virtue of their dependency from independent claim 23. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

**Conclusion**

Applicants respectfully request the reconsideration of this application, the withdrawal of all the outstanding objection and rejections, and the allowance of all pending claims 23-31.

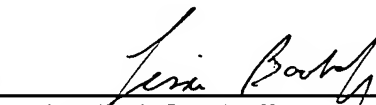
The Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicants decline to necessarily subscribe to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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